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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|

EXAMINER

|          |              |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

|                              |                                  |
|------------------------------|----------------------------------|
| Application No<br>09/364,908 | Applicant(s)<br>Maingault et al. |
| Examiner<br>Jean C. Witz     | Group Art Unit<br>1651           |



Responsive to communication(s) filed on \_\_\_\_\_

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11 453 O.G. 213

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133) Extensions of time may be obtained under the provisions of 37 CFR 1.136(a)

### Disposition of Claim

Claim(s) 1-16 is/are pending in the application

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed

Claim(s) 1-16 is/are rejected

Claim(s) \_\_\_\_\_ is/are objected to

Claims \_\_\_\_\_ are subject to restriction or election requirement

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is approved \_\_\_\_\_ disapproved.

The specification is objected to by the Examiner

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d)

All      Some\*      None      of the CERTIFIED copies of the priority documents have been

received

received in Application No (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e)

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) 4  
Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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***Claim Rejections - 35 USC § 112***

1       Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polysaccharide molecules whose carboxylic acid groups that have been partially esterified with aliphatic chains and whose remaining carboxylic acid groups are linked to a sodium ion, does not reasonably provide enablement for the structures as recited in claim 1 in reference to Figure 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants take a solution of alginic acid macromolecules having a plurality of carboxylic acid groups and neutralize the solution with tetrabutyl ammonium hydroxide (TBA<sup>+</sup>OH<sup>-</sup>) to result in the TBA<sup>+</sup> groups being attached to the carboxylic acid groups on the alginic acid macromolecule (COO<sup>-</sup>TBA<sup>+</sup>). After that, the substituted alginic macromolecules are placed in a solvent along with aliphatic brominated chains of the formula C<sub>n</sub>H<sub>2n-1</sub>Br. The aliphatic C<sub>n</sub>H<sub>2n-1</sub>Br chains are substituted for the some of TBA<sup>+</sup>, in the process losing the Br. Finally, all the remaining TBA<sup>+</sup> are removed and replaced with sodium ions. Applicants disclose that about 92% of the carboxylic acid groups are COO<sup>-</sup>Na<sup>+</sup> and about 8% of the carboxylic acid groups are esterified to aliphatic carbon chains of the formula C<sub>n</sub>H<sub>2n-1</sub>. See the specification, page 7. However, in Figure 1 and Claim 1, it appears that Applicants are attempting to claim specific locations of the esterified carboxylic acid groups such that the modified alginic acid

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macromolecules interact in a known and explicit manner. Given the method of preparation, while Applicants can ascertain the relative amounts of esterified carboxylic groups and sulfated carboxylic groups, it is not ascertainable exactly which groups on any given alginic acid macromolecule will be esterified and which will be sulfated since each macromolecule is essentially a polymer of varying proportions of D-mannuronic acid and L-guluronic acid linked through the 1- and 4- positions.

2. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "system" fails to particularly point out and distinctly claim the subject matter. A statutory category of invention, such as "composition" or "compound", as appropriate, is suggested. Use of the numbers in the claims renders the claims vague and indefinite. While it is understood that Applicants are referring to numbered aspects of Figures 1 and 3-6, they do not clearly point out the metes and bounds of the claims. Claim 11 does not have any positive method steps and therefore fails to comport with U.S. Patent practice.

#### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

4 Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Francesco et al

The reference teaches hydrogel compositions comprising esterified polysaccharide macromolecules (alginic acid or hyaluronic acid) with aliphatic chains which can exist either as a gel or can be solubilized. The aliphatic chains can be attached either via tetrabutyl ammonium salts of the carboxylic acid residues of the macromolecules or via esterification of the carboxylic acid residues with an aliphatic amine. The remaining carboxylic acid residues are converted to sodium salts. See, for example, Example 2 and Column 13, lines 15-50. It is inherent in the disclosure of these molecules that interactions occur between the aliphatic chains of various macromolecules. The aliphatic chains are disclosed as preferably having 6 carbons. Finally, medicaments are combined with the hydrogels as a drug delivery system.

5 Claims 1-2, 4-11 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9637519.

The reference teaches hydrogel compositions comprising esterified polysaccharide macromolecules (alginic acid or hyaluronic acid) with aliphatic chains which can exist either as a gel or can be solubilized. The aliphatic chains are attached either via tetrabutyl ammonium salts of the carboxylic acid residues of the macromolecules. The remaining carboxylic acid residues are converted to sodium salts. It is inherent in the disclosure of these molecules that interactions occur between the aliphatic chains of various macromolecules. The aliphatic chains are disclosed

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as preferably having 6 carbons. Finally, medicaments or cells are combined with the hydrogels as a drug delivery system or as a support for the transplantation of cells.

***Claim Rejections - 35 USC § 103***

6 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7 Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francesco et al. combined with wO 9637519.

It is clear that partial esterification of alginic acid or hyaluronic acid with aliphatic chains is conventional. Both references engage in the same processes as disclosed by Applicants and use aliphatic chains having myriad of different lengths and chemical character. Chains of about 6

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carbons are conventionally used. These modified polysaccharide molecules can exist as hydrogels or in solution, and are conventionally used as delivery vehicles for medicaments and for support for transplantation of cells. Finally, it is clear that selecting the specific aliphatic chain and the degree of esterification is well within the skill of the practitioner such that optimization of specific gel-sol parameters as desired would have been obvious to one of ordinary skill in the art at the time the invention was made.

8. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 4:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



JEAN C. WITZ  
PRIMARY EXAMINER